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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/484,331	01/18/2000	John J. Harrington	5817-7L	9576

959 7590 02/16/2005

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EXAMINER	
WOITACH, JOSEPH T	
ART UNIT	**PAPER NUMBER**
1632	

DATE MAILED: 02/16/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action Before the Filing of an Appeal Brief	Application No. 09/484,331	Applicant(s) HARRINGTON ET AL.	
	Examiner Joseph T. Woitach	Art Unit 1632	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 03 January 2005 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:
   a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.
   b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

   Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The reply was filed after the date of filing a Notice of Appeal, but prior to the date of filing an appeal brief. The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☐ They raise the issue of new matter (see NOTE below);
   (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).
4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
   The status of the claim(s) is (or will be) as follows:
   Claim(s) allowed: _____.
   Claim(s) objected to: _____.
   Claim(s) rejected: *69 and 70*.
   Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08 or PTO-1449) Paper No(s). _____
13. ☐ Other: _____.

Joel Woitach
AU 1632

Continuation of 11. does NOT place the application in condition for allowance because:

Applicants traverse the enablement and written description rejections made under 35 USC 112, first paragraph. With respect to the written description Applicants argue that the Dhanoa Declaration has not been fully considered, and that written description can be inherent citing In re Lukach and Ralston Purina Co. v. Far-Mar-Co, Inc. Specfically, Applicants argue that each Dhanoa and the previously filed Declaration of Bennani provide evidence that one of skill in the art would view the claimed methods to be supported by the instant specification as methods of drug discovery. It is argued that the examiner has not provided any evidence contradicting the expert opinion provided by the declarations (pages 6-9 and 11-12). Further, it is argued that there is no basis for questioning the basis of Dhanoa review of the case history or conclusions therefrom (pages 9-10) and that in fact Dhanoa has reviewed the application in question (pages 10-11). With respect to the enablement rejection Applicants argue that in addition to comments provided in traverse of the written description rejection that one of ordinary skill in the art would have understood that the claimed invention is adequately disclosed, it is only a simple matter to whether the artisan could practice steps (a)-(e) (page 12-14). It is noted that since the method requires that a desired gene be used, by definition it is known and its properties/characterisitcs have been defined, and that testing and assessing any compound with a desired gene would be routine offering several examples of how the skilled artisan would assay for a particular phenotype without any need to know the compound that is being tested (pages 15-17).

Applicants arguments have been fully considered and not found persuasive. The essential issue is whether the mere statement that something is contemplated for use in "drug discovry" would support claim language and enable a disclosure for any method possibly known/used at the time of filing. Applicants' arguments that written description can be inherent citing In re Lukach are noted however the fact pattern of the case clearly supports the instant rejection(s) of record (both written description and enablement) In affirming the position of office, the court noted that 'description of a single embodiment of abroadly claimed subject matter constitutes a description of the invention for anticipation purposes..., whereas the same information in a specification might not alone be enough to provide a description of that invention for purposes of adequate disclosure". In the instant application not even a single species is disclosed of the large geneus of any potential method, let alone any detail for the breadth of knowledge required to practice any method with any gene of interest. The declaration of Bennani and Dhanoa have been fully considered, and do not appear to have been ignored or dismissed. As indicated previously, it has been found that the declarations fail to provide any objective evidence for the conslusions regarding the specifically claimed invention. As noted by Applicants, it is note contested that methods of drug discovery were known and used at the time of filing. The issue again is whether the statement that a product will be used for "drug discovery" would support a claim for any specific method of drug discovery that was known or could be implied from a disclosure that does not provide any guidance to any particular method. To accept Applicants arguments and the conslucsion arrived by the declarants would allow one to insert any amendment to the claims and specification that could have been fabricated and practiced at the time fo filing. Howver, the courts have found that this in not standard for written description. It appears that applicant is attempting to satisfy the written description requirement of 35 USC 112, first paragraph, through obviousness. Obviousness, however, cannot be relied upon for satisfaction of the written description requirement. In support of this position, attention is directed to the decision in University of California v. Eli Lilly and Co. (Fed. Cir. 1997) 43 USPQ2d at 1405, citing Lockwood v. American Airlines Inc. (Fed. Cir. 1997) 41 USPQ2d at 1966: Recently, we held that a description which renders obvious a claimed invention is not sufficient to satisfy the written description requirement of that invention. further, it is noted that the claims have been amended during prosecuation to address rejections made under 35 USC 102. Neither the declaration addresses why the statement of use for "drug discovery" allows one to amend claims to differentiate it from the prior art. This being the same body of art on which Applicants rely and imply provides support for the instantly claimed invention. With respect to the specific examples of successful strategies of drug discovery, noe used "RAGE" technology, and while cell-based and protein-based assays may have been used in development, there is no evidence and appears that none of the specific examples and strategies used artificially expressed endogenous "genes of interest". With respect to the enablement rejection, a prima facie case has been made that in view of the lack of specific guidance in the specfication and absences of any working examples for the huge breadth of suing any methodology with any gene of interest in the field of drug discovery would be considered undue experimentation. Prior successful strategies have used tools, i.e. cells, animal models, that were well characterized and found in the art to be appropriate models of a particular disease or condition. Applicnats arguments that use of a "gene of interest" implies knowledge of said gene in not found convincing. Clearly the use of an artificial promoter to drive expression of a gene or generatte a phenotype would not represent something found in nature, or specifically represent a disease state. While the endogenous gene that is expressed by "RAGE" technology may be implicated in a disease state, the artificial nature of the celll would require adequate characterization to establish whether it can be used as a model system. Moreover, even though a gene may be of interest and have some aberrant expression in certain diseases, sufficient characterization of the disease state for the role of the gene of interest must be done to establish that it is more than just a marker for a disease, and if more than a marker to establish the role of the gene in the disease. Merely stating that the gene is of interest with the implication that it is expressed is insufficinet to establish the resulting cell product would even be an appropirate model system for drug discovery.

Applicants arguments and declarations have been fully considered but not found persuasive for the reasons above and of record, and the rejections are maintained.